

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-16, 18-39, and 41-49 are in this Application. Claims 1-16, 18-39, and 41-49 have been rejected under 35 U.S.C. § 103. Claims 1 and 23 have been amended herewith.

35 U.S.C. § 112 Rejections

Examiner rejected claims 1-16, 18-22, 46, 47 and 49 under 35 U.S.C. § 112. Examiner says that claim1 recites in the limitation "said bone" in line 11 of the claim and that there is insufficient antecedent basis for the limitation in the claim. Applicant in response replaces the term "bone" in claim1 with the term "anatomical structure". The other claims are dependent on claim 1 and are now believed to be allowable in this respect.

35 U.S.C. § 101 Rejections

Examiner rejects Applicant's argument (1). Examiner says that to qualify as a 101 statutory process, the claim should positively recite any other statutory class to which it is tied or positively recite the subject matter that is being transformed. Applicant, in response amends claim 1 by tying the body of the claim to an imaging apparatus. It is believed that the rejection is thereby overcome.

The present invention is directed to a method and apparatus for pre-planning and simulating of orthopedic surgical procedures performed on anatomical structure using medical images. The method comprises, providing a real dimension unit defining a length to appear in an image alongside the anatomic structure for providing calibration of the imaged anatomical structure and using the real dimension unit calibration to provide a scale for identifying the bones for determining an extent of trauma present in the bones.

Kraus discloses a device and method for implementing a computer aided surgical procedure utilizing intra operative feedback. The method comprises three dimensional software for modeling of the area of the patient upon which a surgical procedure is to be performed and for generating the surgical procedure. The surgical procedure may be updated. The three dimensional model may be compared with the 3D pre-surgical bone model to give feedback to a robot or surgeon to follow up the surgical plan more accurately.

Examiner rejects Applicant's arguments (3)-(5). Examiner says that Krause et al. expressly discloses that "the present invention may be used in cases of multiple traumas with long bone fractures" and that "the surgeon may take a fluoroscopic or other image of the fracture and apply the present system to obtain an exact realignment of the fractured bone".

Applicant raises a new argument against the rejection under 35 U.S.C. 103(a) by explaining that Krause compares his model with a generalized 3D model of the particular area of bone he is dealing with. Such a 3D model is not a real dimension unit since it does not provide a real dimension at all. The present application, by contrast uses a real dimension unit alongside the anatomic structure for calibrating the anatomical structure.

Krause uses his model for the purpose of comparing the model of the area of the patient upon which a surgical procedure is to be performed with a model of the particular area of bone he is dealing with. The comparison is done for getting feedback about the correction of the surgery. Paragraph 5 line 11-15 in Krause state

"The actual geometry is compared with the 3D pre-surgical bone model to give feedback to the robot or surgeon while performing the surgery. This feedback allows a robot or a surgeon to follow the surgical plan more accurately than without the sensors." The present application, by contrast, utilizes the real dimension unit for calibration purposes, which is done for recognizing the bones in the first place by obtaining an absolute dimension and then determining an extent of trauma present in the bones. The calibration may include histogram equalization, brightness and contrast adjustments, edge detection dimension calibration, correction for image distortion and the like. Page 10 lines 23-32 and page 11 lines 1 -3 state "Calibration and scaling may include various operations of image enhancements that are commonly used in displaying of images. Images may be enhanced by performing histogram equalization, brightness and contrast adjustments, edge detection, etc. Calibration and scaling may also include dimension calibration for registration with additional objects such as fixation elements as will be explained hereinafter. A common way for acquiring a real dimension unit in the image is to add an object of a known length to be imaged with the imaged subject. Calibration and scaling may also include correction for image distortion as many imaging devices create distortion during imaging. Distortion correction may be performed by applying non-linear correction functions on the original image. These functions are typical to an imaging device and once these functions are created, any image taken by the device may be corrected and the distortion may be reduced to an acceptable minimum."

Krause compares the generated model of the area that needs to be treated with a model of the same area. The only differences between the models is that one model is generated from an area of the body that needs to be fixed while the other model is generated from the same area of the body which is in normal condition. Paragraph 5 lines 11-12 in Krause states "The actual geometry is compared with the 3D pre-surgical bone model to give feedback to the robot or surgeon while performing the surgery." Paragraph 5 lines 61- states "a 3D model of a "normal" or properly aligned reference may be generated. This "template bone model"... may be generated based on representative bone topographic from MRI or CAT data, or data from any other imaging techniques." The present application, by contrast, may use an image of any object for the calibration. Page 10 lines 28-30 state ". A common way for

acquiring a real dimension unit in the image is to add an object of a known length to be imaged with the imaged subject."

Krause performs the comparison between the models during the process of the surgery in order to obtain feedback. Paragraph 5 line 11 in Krause states "The actual geometry is compared with the 3D pre-surgical bone model to give feedback to the robot or surgeon while performing the surgery." The present application, by contrast performs the comparison between the models prior to the surgery for the purposes of calibrating the image by the pre operative planning system as explained in figure 1.

Claims 1 and 23 have been changed to reflect the fact that the calibration is done in order to obtain an absolute dimension of the anatomical structure thereby to provide said absolute length of the anatomical structure. The claims also recite that the real dimension unit appears alongside the anatomical structure. The currently amended claims are believed to be patentable over Kraus. Claims 1-6 and 18-22 are depend from claim 1, and hence the present amendment is believed also to overcome the rejection of claims 1-6 and 18-22. Claims 24-39 and 41-49 are depend from claim 22, and hence the present amendment is believed also to overcome the rejection of claims 24-39 and 41-49.

In view of the above amendments and remarks it is respectfully submitted that claims 1-16, 18-39, and 41-49 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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Enclosures:

- Petition for Extension (Three Months)
- Request for Continued Examination (RCE)